UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

DATE: September 12, 2003

SUBJECT: Fenthion Response to LCMCD Comments

TO: Fenthion RED Team

FROM: Jackie Mosby, Acting Branch Chief
Reregistration Branch 1
Special Review and Reregistration Division

During the comment period for Bayer Environmental Science's (Bayer) voluntary cancellation request for its fenthion registrations, the Agency received three sets of comments in support of the cancellation. After the close of the comment period, but before the Agency made its final determination on the cancellation request, the Agency received one additional set of comments. The additional set of comments supports the continued registration of fenthion products. The Agency reviewed all of the comments and decided to grant Bayer's voluntary cancellations. Please see the Federal Register Notice titled "Fenthion; Product Registrations Cancellation Order" (FRL-7324-2) for details on the cancellation order. This memorandum specifically responds to the set of comments in support of continuing the fenthion registrations.

The submitter of the comments provided the following reasons for supporting the continued registration of fenthion:

1. **No Adverse Effects Associated with Use of Fenthion**

The commenter made the statement that "Lee County Mosquito Control District, Fort Myers, Florida, has been applying fenthion for adult mosquito control since July 2, 1965, without any adverse effects to the environment, including birds." The commenter cites as evidence the fact that fenthion has been sprayed in the area around or adjacent to the J.N. "Ding" Darling National Wildlife Refuge, located on Sanibel Island, for ten years, and there have been no bird kills in the refuge associated with the spraying of fenthion.

Agency Response

The Agency commends the commenter for its diligence in spraying and compliance with the label directions. As such, there should be no incidents on the refuge as long as fenthion is being applied according to the label directions. Spraying is not allowed over the refuge, and drift into that area should not be occurring; therefore, there should be no incidents, as there is no

exposure. The real question concerning risk to birds is whether birds that are in sprayed areas are adversely affected. The information provided on the Ding Darling refuge is not probative of that point.

Non-target species (i.e. birds) in areas where fenthion is sprayed, however, could be adversely affected. The Agency's Interim Reregistration Eligibility Decision (IRED) on fenthion concluded that acute dietary risk to birds from mosquito adulticide applications was "high" based on available information. The Agency also found "that fenthion spraying, especially repeated at frequent intervals, may cause mortality in a variety of bird species."

The IRED also discusses a number of incidents of bird mortality resulting from the spraying of fenthion. The IRED focuses particularly on incidents reported by the US Fish and Wildlife Service (FWS) that occurred on Marco Island. According to the FWS, spraying of fenthion resulted in mortality of at least 16 bird species over approximately an eleven-month time span. See memorandum by W. Erickson, re: Fenthion Marco Island Incidents. The Agency is also aware of a number of other bird incidents related to fenthion. See memorandum from M. Powell to K. David, re: Addendum to EFED's IRED Chapter for Fenthion, Based on Incident Reports (July 31, 1996).

EPA does not believe that the information provided on the J.N. "Ding" Darling National Wildlife Refuge demonstrates that fenthion does not present an unreasonable risk of adverse effects to birds.

2. **More Than One Pesticide for Mosquito Control Needed**

The commenter stated that there are "few tools for public that public health vector control specialists currently have available for adult mosquito control." The commenter stated that there are two products available that are equally efficacious for public health control, fenthion and naled, but that both are necessary in rotation in order to avoid pest resistence issues.

Agency Response

The Agency agrees with the commenter that naled is an efficacious and appropriate alternative to fenthion. The Agency also agrees that it is useful to have more than one "tool"available to address a pest problem. However, when the Agency considered the risks and benefits for fenthion, as required by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the risks posed to birds and aquatic invertebrates were found to outweigh the benefits from its use.

3. **There Are Problems with the Alternatives to Fenthion**

The commenter stated that alternatives other than naled, such as synthetic pyrethroids and malathion may not be used in Lee County, Florida, or in the case of natural pyrethrins, are in limited supply.

Agency Response

The Agency addressed the issue of alternatives to fenthion in the IRED (see IRED Sections IV.E and IV.F). The Agency agrees with the commenter that there may be drawbacks to several of the alternatives; however, naled is an efficacious and appropriate alternative to fenthion, as used in Lee County. FIFRA does not require that multiple alternatives to a pesticide exist in order for the Agency to issue a cancellation order under FIFRA §6(f).

4. **CDC and HHS Appear to Support the Continued Use of Fenthion**

The commenter stated a Department of Health and Human Services (HHS) in the Centers for Disease Control and Prevention (CDC) official, Dr. Duane Gubler, stated that the loss of a single mosquito control tool would "seriously compromise" the CDC's ability to "prevent and control vector-borne disease in the [United States]."

The commenter also stated that the Agency cannot cancel fenthion, in light of its obligations under FIFRA §4(n) to consult, when requested by the registrant, with the HHS before approving a request for a voluntary cancellation.

Agency Response

Bayer requested, pursuant to FIFRA §4(n), that EPA consult with HHS before canceling its fenthion registrations. After consulting with HHS, EPA may determine that the benefits of the public health or vector control pesticide are so significant as to warrant a commitment by HHS to conduct (or arrange to conduct) studies needed to support continued registration of the pesticide. EPA sent a letter to CDC requesting consultation and inviting CDC to submit additional information on fenthion. EPA received a response from HHS, dated August 1, 2003, stating that it does not take exception to our decision to cancel fenthion, but indicating that more than one tool should remain available for mosquito control. EPA believes it has fulfilled its consultation requirement under FIFRA §4(n).

EPA understands that individuals within HHS and CDC may support the continued registration of fenthion; however, even considering available information from HHS and CDC, EPA has yet to find fenthion eligible for reregistration. The Agency does not believe the commenter has provided sufficient justification to merit denying the voluntary cancellation request.

5. **Outstanding Data Requirements**

The commenter stated that there have been discrepancies between the data gaps EPA identified in the IRED and the studies EPA has included in the Data Call-In (DCI) notices. The commenter suggested that there were no outstanding data requirements on which EPA could have pursued suspension or cancellation under FIFRA §4(n) or §6(b). The commenter also appeared to suggest that this confusion led Bayer to conclude that it did not have an economic stake in the fenthion registrations. The commenter referenced three studies in particular: developmental

neurotoxicity, ecotoxicity, and worker exposure.

Agency Response

With respect to the studies the commenter referenced, EPA notes the following:

Developmental neurotoxicity - as the commenter points out, this study was included in a 1999 DCI. Bayer's fenthion registrations were subject to this DCI, and Bayer was required to conduct the study. The commenter suggests that because Bayer went on to cancel the food uses associated with fenthion, the study is not necessary; however, EPA has never waived this data requirement for the fenthion registrations. Therefore, it is still a data gap and would need to be addressed in order for Bayer to continue its fenthion registrations.

Ecotoxicity and worker exposure - while these studies were listed as data gaps in the IRED, EPA decided not to issue a DCI for them, due to the fact that Bayer requested voluntary cancellation of all its fenthion registrations. However, if another registrant chose to apply for a fenthion registration in the future, and EPA determined that the application for registration met the standard for registration and was eligible for reregistration, EPA would either issue a DCI at that time, require that the data gaps be filled before registering the product, or, if appropriate, condition the registration on the fulfillment of the outstanding data gaps.

The Agency is not privy to all the factors, economic and otherwise, Bayer considered in deciding to request voluntary cancellation. In determining whether to grant a voluntary cancellation request, it is immaterial whether EPA could have cancelled the product on its own initiative. Furthermore, EPA does not believe that its failure to issue a DCI for a pesticide (or potential confusion over data gaps) is a reason to deny a voluntary cancellation request. As noted above, EPA has fulfilled its obligation under FIFRA §4(n).